Louisiana Medicaid
Methotrexate

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred methotrexate agents
- Clinical authorization for methotrexate (Otrexup®, Rasuvo®, RediTrex®)

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Non-Preferred Methotrexate Agents (Other than Otrexup®, Rasuvo® and RediTrex®)

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Approval Criteria for Otrexup®, Rasuvo® and RediTrex®

- **ONE** of the following:
    - The recipient is 18 years of age or older on the date of the request; **AND**
        - **ONE** of the following is true and is **stated on the request**:
            - The recipient has a diagnosis of rheumatoid arthritis which is severe and active; **OR**
            - The recipient has a diagnosis of psoriasis which is severe, recalcitrant and disabling; **OR**
    - The recipient is 2 years of age or older on the date of the request; **AND**
        - The following is true and is **stated on the request** – The recipient has a diagnosis of polyarticular juvenile idiopathic arthritis; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- Methotrexate (Otrexup®, Rasuvo®, RediTrex®) is prescribed by, or the request states that the requested medication is prescribed in consultation with, a rheumatologist or dermatologist; **AND**
- The following is true and is **stated on the request**:
    - For rheumatoid arthritis:
        - The recipient has a *contraindication* to, *documented intolerance* or *treatment failure* with an adequate trial (6-12 weeks) of **AT LEAST ONE** non-biologic DMARD (such as oral methotrexate, leflunomide, or azathioprine); **AND**
        - The recipient has the inability to prepare and administer generic injectable methotrexate; **OR**
    - For psoriasis:
        - The recipient has a *contraindication* to, *documented intolerance* or *treatment failure* with an adequate trial (6-12 weeks) of **AT LEAST ONE** of the following therapies: phototherapy, oral methotrexate, and/or cyclosporine; **AND**
        - The recipient (or the caregiver) has the inability to prepare and administer generic injectable methotrexate; **OR**
    - For polyarticular juvenile idiopathic arthritis:
        - The recipient has a *contraindication* to, *documented intolerance* or *treatment failure* with an adequate trial (6-12 weeks) of **AT LEAST ONE** non-biologic DMARD (such as oral methotrexate); **AND**
        - The recipient (or the caregiver) has the inability to prepare and administer generic injectable methotrexate; **AND**

- By submitting the authorization request, the prescriber attests to the following:
    - Methotrexate (Otrexup®, Rasuvo®, RediTrex®) is **NOT** being used to treat neoplastic disease; **AND**
    - Methotrexate (Otrexup®, Rasuvo®, RediTrex®) will not be used concomitantly with any other methotrexate product; **AND**
    - For a diagnosis of psoriasis, the prescriber has ensured that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 3 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; https://www.clinicalkey.com/pharmacology/

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Otrexup (methotrexate) [package insert]. Rockville, MD: Antares Pharma, Inc; December 2019. https://www.otrexup.com/application/files/3715/8619/3267/Otrexup_USPI_-_LB-0027_V11.pdf

Rasuvo (methotrexate) [package insert]. Chicago, IL: Medac Pharma Inc; March 2018. http://cdn.rasuvo.com/assets/pdf/Prescribing-Information-current.pdf

RediTrex (methotrexate) [package insert]. Nashville, TN: Cumberland Pharmaceuticals Inc; August 2020. https://reditrex.com/wp-content/uploads/2020/10/Reditrex-revised-PI_AUG2020-cleanJW.pdf

Revision / Date	**Implementation Date**
Policy created	April 2020
Formatting changes; added non preferred criteria wording; updated references / October 2020	October 2020
Added RediTrex® with reference / May 2021	July 2021